



DOCKET NO.: PHOE-0136

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In Re Application of:**

**Ensor, C.M. et al.,**

**Application No.: 10/645,723**

**Filing Date: August 21, 2003**

**For: NOVEL MUTATED FORM OF ARGININE DEIMINASE**

**Confirmation No.:**

**Group Art Unit: Not Yet Assigned**

**Examiner: Not Yet Assigned**

DATE OF DEPOSIT: *October 24, 2003*

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

*Jane E. Inglese*

TYPED NAME: Jane E. Inglese, Ph.D.  
REGISTRATION NO.: 48,444

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;  
or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☐ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

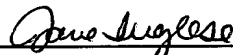
## EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
  - ☒ Copies of references **1 thru 37** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/564,559**, filed **May 4, 2000**.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

There are no listed references which are not in the English language.

Date: *October 24, 2003*

  
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. <b>PHOE-0136</b>	Application No. <b>10/645,723</b>
	Applicant <b>Charles Mark Ensor, et al.</b>	
	Filing Date <b>August 21, 2003</b>	Group <b>Not Yet Assigned</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>		
	1	Abstract J04121187: Japanese Application No. 1992-188063, Derwent Publications Ltd., London, GB, April 22, 1992
	2	Harasawa, R. et al., "Nucleotide Sequence of the Arginine Deiminase Gene of <i>Mycoplasma hominis</i> ," <i>Microbiol. Immunol.</i> , 1992, 36(6), 661-665
	3	Takaku, H. et al., "Anti-tumor Activity of Arginine Deiminase from <i>Mycoplasma arginini</i> and Its Growth-inhibitory Mechanism," <i>Jpn. J. Cancer Res.</i> , September 1995, 86(9), 840-846
	4	International Search Report dated January 11, 2002, issued in corresponding International Application No. PCT/US01/14116
	5	Fraser, C. et al., "Borrelia burgdorferi (section 69 of 70) of the complete genome", 12/16/1997, Database Accession no. AE001183, XP 002211866
	6	Knodler, Leigh A. et al., "Cloning and Expression of a Prokaryotic Enzyme, Arginine Deiminase., from a Primitive Eukaryote <i>Giardia intestinalis</i> ", <i>Journal of Biological Chemistry</i> , 02/20/1998, 273(8), 4470-4477, XP-002211868
	7	Seffernick, J.L. et al., "Melamine Deaminase and Atrazine Chlorohydrolase: 98 Percent Identical but Functionally Different", <i>J. Bacteriol.</i> , 2001, 183(8), 2405-2410
	8	Broun, P. et al., "Catalytic Plasticity of Fatty Acid Modification Enzymes Underlying Chemical Diversity of Plant Lipids", <i>Science</i> , 1998, 282, 1315-1317
	9	Van de Loo, F.J. et al., "An Oleate 12-hydroxylase from <i>Ricinus Communis L.</i> is a Fatty Acyl Desaturase Homolog" <i>Proc. Natl. Acad. Sci.</i> , 1995, 92, 6743-6747
	10	Sugimura, et al., "High Sensitivity of Human Melanoma Cell Lines to the Growth Inhibitory Activity of Mycoplasmal Arginine Deiminase <i>In Vitro</i> , <i>Melanoma Res.</i> , 1992, 2, 191-196
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>



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	<b>11</b>	Takaku, et al., "In Vivo Anti-tumor Activity of Arginine Deiminase Purified from Mycoplasma Arginini", <i>Int. J. Cancer</i> , <b>1992</b> , 51, 244-249
	<b>12</b>	Miyazaki, et al., "Potent Growth Inhibition of Human Tumor Cells in Culture by Arginine Deiminase Purified from a Culture Medium of a Mycoplasma- infected Cell Line", <i>Cancer Res.</i> , <b>1990</b> , 50, 4522-4527
	<b>13</b>	J.B. Jones, "The Effect of Arginine Deiminase on Murine Leukemic Lymphobalsts", <i>Ph.D. dissertation, The University of Oklahoma</i> , <b>1981</b> , 1-169
	<b>14</b>	van Wagtehdonk, et al., "Nitrogen Metabolism in Protozoa", <i>Comparative Biochemistry of Nitrogen Metabolism (J.W. Campbell ed.)</i> , <b>1970</b> , 1-56
	<b>15</b>	Chang, et al., "Arginase Modulates Nitric Oxide Production in Activated Macrophages", <i>Am. J. Physiol: Heart and Circul. Physiol.</i> , <b>1998</b> , 274, H342-H348
	<b>16</b>	McDonald, et al., "A Caveolar Complex Between the Cationic Amino Acid Transporter 1 and Endothrlial Nitric-oxide Synthase may Explain the "Arginine Paradox", <i>J. Biol. Chem.</i> , <b>1997</b> , 272, 31213-31216
	<b>17</b>	Misawa, et al., "High Level Expression of Mycoplasma Aginine Deiminase in Escherichia Coli and its Efficient Renaturation as an Anti-Tumor Enzyme", <i>J. of Biotechnol.</i> , <b>1994</b> , 36, 145-155
	<b>18</b>	Takaku, et al., "Chemical Modification by Polyethylene Glycol of the Anti-Tumor Enzyme Arginine Deiminase from Mycoplasma Argini", <i>Int. J. Cancer Res.</i> , <b>1993</b> , 84, 1195-1200
	<b>19</b>	Abuchowski, et al., "Cancer Therapy with Chemically Modified Enzymes. I. Antitumor Properties of Polyethylene Glycol-Asparaginase Conjugates", <i>Cancer Biochem. Biophys.</i> , <b>1984</b> , 7, 175-186
	<b>20</b>	Abuchowski, et al., "Effect of Covalent Attachment of Polyethylene Glycol on Immunogenicity and Circulating Life of Bovine Liver Catalase", <i>J. Biol. Chem.</i> , <b>1977</b> , 252, 3582-3586
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	<b>21</b>	Parker, et al., "The Effect of Tumor Size on Concomitant Tumor Immunity", <i>Cancer Res.</i> , <b>1973</b> , 33(1), 33-39	
	<b>22</b>	Zaplipsky and Lee, "Use of Functionalized Poly(Ethylene Glycol)s for Modification of Polypeptides", <i>Poly(Ethylene Glycol) Chemistry: Biotechnical and Biomedical Applications</i> (J.M. Harris, ed., Plenum Press, NY), <b>1992</b> , Chapter 21, 247-370	
	<b>23</b>	Fenske, J.D., et al. "Role of Arginine Deiminase in Growth of <i>Mycoplasma hominus</i> ", <i>J. Bacteriol.</i> , <b>1976</b> , 126, 501-510	
	<b>24</b>	Lang, K. et al., "Catalysis of Protein Folding by Prolyl Isomerase", <i>Nature</i> , <b>1987</b> , 329, 268-270	
	<b>25</b>	Craig, S. et al., "Single Amino Acid Mutations Block a Late Step in the Folding of B-Lactamase from <i>Staphylococcus aureus</i> ", <i>J. Mol. Biol.</i> , <b>1985</b> , 185, 681-687	
	<b>26</b>	Joppich, et al., "Peptides Flanked by Two Polymer Chains, 1-Synthesis of Glycyl-L-tryptophylglycine Substituted by Poly(ethylene oxide) at both the Carboxy and the Amino End Groups", <i>Macromol. Chem.</i> , <b>1979</b> , 180, 1381-1385	
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Group  
**Not Yet Assigned**

## U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	27	4,800,159	01/24/89	Mullis, et a.	435	172.3
	28	5,372,942	12/13/94	McGarrity, et al.	435	227
	29	5,474,928	12/12/95	Takaku, et al.	435	228
	30	5,804,183	09/09/98	Filpula, et al.	424	94.6
	31	5,916,793	06/29/99	Filpula, et al.	424	94.6
	32	6,132,713	10/17/00	Fiiipula, et al.	424	94.3

## FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	33	EP 0 414 007 A2	02/27/91	EP		
	34	EP 0 897 011 A2	02/17/99	EP		
	35	WO 98/33519	08/06/98	WIPO		
	36	WO 98/51784	11/19/98	WIPO		
	37	JP 3 209 338 B2	09/17/01	Japan	X (Abstract)	

**EXAMINER**

**DATE CONSIDERED**